AMENDMENTS TO THE CLAIMS

1. (Withdrawn) A nucleic acid molecule comprising an adeno-associated viral vector and a promoter which is operably linked to a sequence encoding bone morphogenetic protein.

2. (Withdrawn) The nucleic acid molecule of claim 1, wherein said promoter is a promoter of bone morphogenetic protein.

3. (Withdrawn) The nucleic acid molecule of claim 1, wherein said promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

4. (Withdrawn) A nucleic acid molecule comprising an adeno-associated viral vector and a promoter which is operably linked to: (a) a nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

5. (Withdrawn) The nucleic acid molecule of claim 4, wherein said promoter is a promoter of bone morphogenetic protein.

6. (Withdrawn) The nucleic acid molecule of claim 4, wherein said promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

7. (Withdrawn) A vector comprising the nucleic acid molecule of any one of claims 1, 2, 3, 4, 5 or 6.

8. (Withdrawn) A host cell comprising the nucleic acid molecule of claim 7.

9. (Withdrawn) A pharmaceutical composition comprising the nucleic acid molecule of any one of claims 1, 2, 3, 4, 5 or 6; and a pharmaceutically acceptable carrier.

10. (Cancelled).

11. (Cancelled).

12. (Cancelled).

13. (Currently amended) A method of treating a disease or disorder in a body area of an immunocompetent subject ~~in need thereof~~ where bone regeneration is required, said method comprising administering locally to said ~~subject~~ body area a therapeutically effective amount of a nucleic acid molecule comprising an adeno-associated viral vector and a promoter which is operably linked to: (a) a nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

14. (Original) The method of claim 13, wherein said promoter is a promoter of bone morphogenetic protein.

15. (Currently amended) The method of claim 13, wherein said promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

16. (Currently amended) The method of claim 13 wherein the nucleic acid molecule is administered to a skeletal muscle of said ~~subject~~ body area.

17. (Withdrawn) A pharmaceutical composition comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein; a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein; and a pharmaceutically acceptable carrier.

18. (Withdrawn) The pharmaceutical composition of claim 17, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

19. (Withdrawn) The pharmaceutical composition of claim 17, wherein said first promoter and/or said second promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

20. (Withdrawn) A host cell comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein; and a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a nucleotide sequence encoding bone morphogenetic protein.

21. (Withdrawn) The host cell of claim 20, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

22. (Withdrawn) The host cell of claim 20, wherein said first promoter and/or said second promoter is a CAG promoter comprising a beta-actin promoter and a cytomegalovirus enhancer.

23. (Currently amended) A method of treating a disease or disorder in a body area of an immunocompetent subject ~~in need thereof~~ where bone regeneration is required, said method comprising administering locally to said ~~subject~~ body area a therapeutically effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter, and a second nucleic acid molecule comprising an adenoviral vector and a second promoter, wherein the first and second promoters are each operably linked to either: (a) a nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

24. (Original) The method of claim 23, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

25. (Currently amended) The method of claim 23, wherein said first promoter and/or said second promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

26. (Currently amended) The method of claim 23, wherein said first and second nucleic acid molecules are administered concurrently to a skeletal muscle of said ~~patient~~ body area.

27. (Withdrawn) A pharmaceutical composition comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a nucleotide sequence encoding a polypeptide; a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a nucleotide sequence encoding the polypeptide; and a pharmaceutically acceptable carrier.

28. (Withdrawn) A host cell comprising a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a first nucleotide sequence encoding a polypeptide; and a second nucleic acid molecule comprising an adenoviral vector and a second promoter which is operably linked to a second nucleotide sequence encoding a polypeptide.

29. (Currently amended) A method of treating a ~~disease or disorder in a~~ diseased or injured body area of an immunocompetent subject ~~in need thereof~~, said method comprising administering locally to said ~~subject~~ body area a therapeutically effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a first nucleotide sequence encoding a ~~polypeptide~~ therapeutic gene product; and a second nucleic acid molecule

comprising an adenoviral vector and a second promoter which is operably linked to a second nucleotide sequence encoding a ~~polypeptide~~ therapeutic gene product.

30. (Currently amended) The method of claim 23 or 29, wherein ~~the amount of the first nucleic acid molecule is higher than the amount of the second nucleic acid molecule~~ the adenoviral vector is administered at an amount that is non-toxic and non-immunogenic in the subject.

31. (New) The method of claim 29, wherein the said first and/or second promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

32. (New) The method of claim 13, 23 or 29, wherein the subject is a human.

33. (New) The method of claim 13 or 23, wherein the disease or disorder is selected from the group consisting of bone fracture non-union, segmental bone defects, spinal fusion, periodontal disease, degenerative disc disease, and growth plate injury.

34. (New) The method of claim 29, wherein the diseased body area is inflicted with cancer.

35. (New) A method for expressing a bone morphogenetic protein (BMP) for new bone formation in a body area of a subject, comprising administering locally to said body area an effective amount of a nucleic acid molecule comprising an adeno-associated viral vector (AAV) and a promoter which is operably linked to a nucleotide sequence encoding the BMP.

36. (New) The method of claim 35, wherein said BMP is BMP-2.

37. (New) The method of claim 35, wherein the nucleotide sequence encoding the BMP has: (a) the nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

38. (New) The method of claim 35, wherein said promoter is a promoter of the BMP.

39. (New) The method of any one of claims 35-37, wherein said promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

40. (New) The method of claim 35, wherein the nucleic acid molecule is administered to a skeletal muscle of said body area.

41. (New) A method for expressing a bone morphogenetic protein (BMP) for new bone formation in a body area of a subject, comprising administering locally to said body area an effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter, and a second nucleic acid molecule comprising an adenoviral vector and a second promoter, wherein the first and second promoters are each operably linked to a nucleotide sequence encoding the BMP.

42. (New) The method of claim 41, wherein said BMP is BMP-2.

43. (New) The method of claim 41, wherein the nucleotide sequence encoding the BMP has: (a) the nucleotide sequence of SEQ ID NO:1; or (b) a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

44. (New) The method of claim 41, wherein the amount of the adenoviral vector is a dosage that is non-toxic and non-immunogenic in the subject.

45. (New) The method of claim 41, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

46. (New) The method of claim 41, wherein said first promoter and/or said second promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

47. (New) The method of claim 41, wherein said first and second nucleic acid molecules are administered concurrently to a skeletal muscle of said body area.